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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,553	11/05/2001	Jan Yngvar Piene	288748.0003	5786

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EXAMINER
KHARE, DEVESH

ART UNIT	PAPER NUMBER
1623	7

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,553	PIENE ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-14 are currently pending in this application.

Objections

Claim 9 improperly depends on itself.

Appropriate correction is required.

35 U.S.C. 112, first paragraph rejection

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Many of the factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The relative skill of those in the art;

(7) The predictability or unpredictability of the art; and

(8) The breadth of the claims.

The applicant's specification fails to provide sufficient guidance or support to enable the worker of ordinary skill in the art to practice a process for obtaining a physiologically

tolerable particulate calcium compound of claim 1 (i). The specification describes the alleged process for obtaining physiologically tolerable particulate calcium compound in a prophetic manner only. Such allegations are not considered to provide sufficient support for obtaining physiologically tolerable particulate calcium compound, particularly since there is not seen sufficient guidance and support in the specification or correlation of that which is disclosed with prior art teachings to support same.

Further, there is no enabling description for obtaining physiologically tolerable particulate calcium compound having a mean particle size in the range 3 to 40 μm, having a crystalline structure and having a surface area of 0.1 to 1.2 m^2/g. The worker of ordinary skill in the art would not be able to practice the instantly claimed method given the limited guidance provided by the disclosure herein. It is well known and established that the "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.,* 166 USPQ 138(CCPA 1970).

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 1-14 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "optionally mixing said first granulate with one or more further components" in claim 1 (iii) is a relative phrase, which renders the claim indefinite. The phrase "optionally mixing said first granulate with one or more further components" is not defined by the claim, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, specifically in view of the fact that the claims fail to particularly point out the distinct identity of the "potential" further components.

Claim 6 lack antecedent basis for the phrase "in step (i) the same material is used as said diluent and as said binder" (i.e. it has not been established that this phrase is related to claim 3).

In claims 4 and 5, the terms "68 to 80% wt" and "60 to 95% wt" are unclear. It is unclear whether the "% wt" is a percent by weight ratio or of the total weight ratio.

Claim 12 lacks antecedent basis for the phrase "first granulate has a particle size distribution of" (i.e. it has not been established that this phrase is related to claim 3).

Claims 8 and 13 set-forth improper Markush terminology. The language "selected from" at line 2 should be changed to –at least one component selected from the group consisting of--.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentine (EP 0192460) in view of Walsdorf et al. (U.S. Patent 4,814,177).

Claims 1 is drawn to a process for the preparation of an orally administrable calcium composition which is comprised of:

Obtaining a particulate calcium compound having a mean particle size in the range 3 to 40 μm, having a crystalline structure and having a surface area of 0.1 to 1.2 m^2/g and producing a first granulate by mixing the said calcium compound with a water soluble diluent and an aqueous solution of a binder in a fluid bed granulation apparatus and further drying the resulting mixture; optionally producing a second granulate by mixing the first granulate with one or more components; and optionally compressing first or second granulate to form tablets.

Further claim limitations include specific calcium compounds, the amount in wt% of calcium in the first or second granulate,calcium compound is mixed with isoflavone, the

diluent and binder are same material, wherein the diluent is at least one sweetener, binder is a specific compound..

Applicants also claim (claim 12) the particle size distribution of first granulate and additional components mixed with the first granulate selected from vitamin B6, vitamin K, vitamin C, vitamin D, isoflavones, inulin and oligofructose and mixtures.

Valentine teaches processes for making agglomerates and tablets in a tablet forming apparatus (see abstract). Valentine disclosed insoluble metal and mineral hydroxides and carbonates as active ingredients in the agglomerates (see p. 6, lines 18-20). Valentine disclosed a process for making the carbohydrate-based agglomerate comprising the said active ingredients in tablet form by mixing the active ingredients with a water-soluble diluent and an aqueous solution of a water soluble binder to produce the first agglomerate or granulate and then mixing lubricant or flavors to produce the second agglomerate or granulate (see p.7, line 19- p.9, line 2). Valentine disclosed a water-soluble binder or sweetener selected from the group consisting of maltodextrine and polyvinylpyrollidone on p. 4, lines 15-17. Also see page 20, lines 2-15, wherein the liquid binder solution and carbohydrate particles including maltodextrin, fructose, sucrose and polyvinylpyrollidone are listed present in the agglomerates or granulates. "A well known sweetener, used as a binder will still be a sweetener, or sweet" in a composition. It is noted that Valentine does not provide specific disclosures regarding a calcium compound mixed with isoflavones or vitamins, however, Valentine

suggest on p. 12, lines 1-10, the use of the said process for making vitamin tablets and dietary supplement and nutrient tablets. Furthermore, under Example XIII (process) on p. 29-30, up to 76.6% wt. of calcium carbonate with a particle size of 3-10 μm is disclosed. It is noted that the present invention is directed to a process to produce a calcium tablet with a calcium compound content in excess of 60% by weight (see specification page 2, lines 1-5). Valentine differs from the applicant's invention in that Valentine does not provide an explicit example of a specific surface area of calcium compound, however Valentine does provide motivation to use a process to produce an orally administrable calcium composition with a calcium compound content in excess of 60% by weight (see p. 2, lines 21-24). Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

Walsdorf et al. teach a calcium citrate tableting composition containing sugar, polyvinylpyrrolidone and calcium carbonate (see abstract) and a method for producing the same (see claims 1-8). Walsdorf et al. disclose the studies of surface area of calcium citrate composition to understand the greater compressible nature of the calcium citrate composition on col. 5, lines 9-27, disclosing the surface area range for the calcium citrate composition between about 0.7 m^2/g and about 2.0 m^2/g. Walsdorf et al. also disclose in Example 16, col.14, the x-ray analysis of calcium citrate to study the compressibility of the calcium citrate. It is noted that Walsdorf et al. does not provide specific disclosures regarding a process for producing a calcium compound

composition with calcium content in excess of 47.5 weight percent (see col. 3, lines 40-43).

Therefore, one of ordinary skill in the art would have found the applicants claimed process for the preparation of an orally administrable calcium composition, to have been obvious at the time the invention was made having the above-cited references before him. Since Valentine teaches processes to produce an orally administrable calcium composition with a calcium compound content in excess of 60% by weight especially up to 76.6% wt. of calcium carbonate with a particle size of 3-10 μm and Walsdorf et al. disclose a method for producing a calcium citrate tableting composition containing the surface area range for the calcium citrate composition between about 0.7 m^2/g and about 2.0 m^2/g, one skilled in the art would have a reasonable expectation for success in combining both references to obtain an orally administrable calcium composition. The motivation for doing so is provided in the prior art, which discloses the process to produce an orally administrable calcium composition with a calcium compound content in excess of 60% by weight is desirable for reducing the size of calcium citrate containing tablets, and providing dietary calcium supplementation.

State of the Art References

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Upson et al. (U.S. Patent 5,629,013)- discloses a calcium carbonate antacid tablet composition.

Gurol et al. (U.S. Patent 6,066,342)- discloses an antacid composition containing 20 to 75 weight percent calcium carbonate.

Tiongson (U.S. Patent 6,368,638)- discloses a process of making an aqueous calcium carbonate suspension.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
April 29,2003